DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 23, 2015

Cayenne Medical, Incorporated
Ms. Shima Hashemian
Senior Quality Assurance/Regulatory Affairs Manager
16597 North, 92nd Street
Scottsdale, Arizona 85260

Re: K143392
Trade/Device Name: Quattro® Bolt Tenodesis Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 25, 2014
Received: November 26, 2014

Dear Ms. Hashemian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: Quattro® Bolt Tenodesis Screw

Indications for Use:

The Cayenne Medical, Inc. Quattro® Bolt Tenodesis Screws are intended to be used for the reattachment of soft tissue to bone for the following indications:

Shoulder

- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff repairs
- Biceps tenodesis

Elbow, Wrist, and Hand

- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair

Knee

- Extra-capsular repairs
    - Medial collateral ligament
    - Lateral collateral ligament
    - Posterior oblique ligament
- Patellar realignment and tendon repairs
- Illiotibial band tenodesis

Foot and Ankle

- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Cayenne Medical, Inc.

Quattro® Bolt Tenodesis Screw

ADMINISTRATIVE INFORMATION

Date of summary:	11/25/2014
Manufacturer Name:	Cayenne Medical, Inc. 16597 N. 92nd St., Suite 101 Scottsdale, AZ 85260 Telephone (480) 502-3661 FAX (480) 502-3670
Official Contact:	Shima Hashemian 16597 N. 92nd St., Suite 101 Scottsdale, AZ 85260 shashemian@cayennemedical.com Telephone (480) 502-3661 FAX (480) 502-3670

DEVICE NAME

Classification Name:	Smooth or threaded metallic bone fixation fastener
Trade/Proprietary Name:	Quattro® Bolt Tenodesis Screw
Common Name:	Screw

DEVICE CLASSIFICATION

FDA has classified bone fixation fasteners as Class II devices (21 CFR 888.3040). The product code for fastener, fixation, nondegradable, soft tissue is MBI. These devices are reviewed by the Orthopedic Joint Devices Branch. These devices are reviewed by the Orthopedic Joint Devices Branch.

INTENDED USE

The Cayenne Medical, Inc. Quattro® Bolt Tenodesis Screws are intended to be used for the reattachment of soft tissue to bone for the following indications:

Shoulder
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff repairs
- Biceps tenodesis

Elbow, Wrist, and Hand
- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair

Knee
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
- Illiotibial band tenodesis

Foot and Ankle
- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy

DEVICE DESCRIPTION

The Quattro® Bolt Tenodesis Screw is a sterile (using gamma radiation method), manually operated, single procedure device for reattachment of soft tissue to bone. The Quattro® Bolt screw is preloaded on a disposable driver. Quattro® Bolt device incorporates design features that facilitate screw placement under arthroscopic, open, or limited access conditions in soft tissue to bone reattachment procedures.

The Quattro® Bolt tenodesis screw is offered in 5 different sizes, 5mm×10mm, 6mm×12mm, 7mm×14mm, 8mm×16mm, 9mm×16mm. The screws are made out of PolyEtherEtherKetone (PEEK).

The disposable driver has a working shaft length of 14cm with an outer shaft diameter of 3.0 mm. The driver shaft is made out of surgical grade stainless steel and the handle is made out of ABS plastic.

NON-CLINICAL TESTING

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence is included. Mechanical testing (pull-out strength) was performed on the Quattro® Bolt tenodesis screw and the predicate device. Testing showed that the Quattro® Bolt tenodesis screw ultimate pull-out strength was comparable to that of the predicate device.

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Quattro® Bolt tenodesis screw is substantially equivalent in indication and design principles to predicate device, which has been determined by FDA to be substantially equivalent to preamendment devices: Quattro® Link Knotless Anchor with Inserter (K122314). The substantial equivalence of Quattro® Bolt tenodesis screw is based on similarities in indications for use, intended use, design features, technology, and materials to the predicate device.

The subject Quattro® Bolt device has the same intended use as the predicate device, the Quattro® Link.

This subject device differs from the predicate device, Quattro® Link Knotless Anchor with Inserter, in terms of the implant design and the offered sizes.